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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/650,027 | 08/27/2003 | Fred H. Burbank | R0367.00302 | 6463 |
| 7590 | 10/11/2005 | | EXAMINER | |
| Edward J. Lynch DUANE MORRIS LLP Spear Tower, Ste. 2000 One Market San Francisco, CA 94105 | | | MARMOR II, CHARLES ALAN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,027

Applicant(s)

BURBANK ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30, 32-38, 40-54 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-47 and 58-60 is/are allowed.
- 6) ☒ Claim(s) 28-30, 32-38, 40, 41, 48, 61 and 62 is/are rejected.
- 7) ☒ Claim(s) 49-54, 56 and 57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 9, 2005 has been entered.

The Examiner acknowledges the amendments to claims 28, 32, 33, 42, 44, 48, 58, 59, 61 and 62, and the cancellation of claim 31. Claims 28-30, 32-38, 40-54 and 56-62 are pending.

Drawings

2. The drawings are objected to because the lower portions of Figures 1, 5, 6, 9, 10, 15 and 16 have been truncated. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after

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the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 28 is objected to because of the following informalities: at line 15, --a-- should be inserted before "diameter". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 61 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 61 recites that an elongated cutting member is slidably disposed within the elongated shaft. Claim 62 recites that an elongated cutting member is slidable within the inner lumen of the elongated shaft. The disclosure of the present application does not provide support for these limitations. The specification of the present application defines a stylet shaft and a

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cannula shaft that may be considered to be the claimed elongated shaft of claims 58 and 62. If the stylet shaft is considered to be the claimed elongated shaft, the stylet shaft has an inner lumen in which a conductor is disposed. The disclosure does not recite that any cutter member is disposed within the inner lumen of the stylet shaft. Alternatively, if the cannula shaft is considered to be the claimed elongated shaft, the cannula shaft includes an inner lumen and a cutting element that has a cutting surface transversely disposed with respect to a longitudinal axis of the cannula shaft. The cutting element is disclosed mounted in the inner lumen of the cannula shaft and slideable *with* the cannula shaft. At no time in the disclosure of the present application is an elongated cutting member with a cutting surface transversely disposed relative to the longitudinal axis disclosed as being *slidably disposed within* a shaft or an inner lumen of a shaft, as recited in claims 61 and 62.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 28-30, 32-38, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 28, the limitation “and which has an outer diameter...” is recited at line 14. The claim language is unclear as to whether this limitation is directed to the “elongate stylet” (recited at line 9) as a whole or the “distal end” (recited at line 12).

Regarding claim 34, it is unclear whether the claim is consistent with the limitations of independent claim 28. First, it is unclear whether a second tissue cutting element including an

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apex portion of a conical stylet head can be accurately said to “lie in a *plane* parallel with the longitudinal axis of said cannula” as recited in lines 19-20 of claim 28. Second, the Brief Description of the Drawings at page 6, lines 16-18; the specification at page 8, lines 18-25; and the reference signs in Figure 16 indicate that the figure only illustrates an elongate stylet. In view of the foregoing, it is unclear how the stylet head of this embodiment can be accurately said to have an outer diameter which is greater than a diameter of the inner lumen of the open distal end of the cannula.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 48 is rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al. ('955). Bryan et al. teach a biopsy apparatus including an elongate cannula (24) having a longitudinal axis, an open distal end, a proximal end, an inner lumen extending to and in fluid communication with the open distal end and a longitudinal axis; a first tissue cutting element (50) disposed on the open distal end of the cannula lying in a plane traversing the longitudinal axis of the cannula and having a transverse dimension; an elongate stylet (16) which is slidably disposed in part within the inner lumen of the cannula, which is configured for axial translation between a withdrawn position and an extended position and which has a distal end (13) configured (at 52)

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to receive the first tissue cutting element; and a second tissue cutting element (see at least Figures 3, 6, 12, 14 and 15) which is disposed on a distal end (13) of the stylet distal to the first tissue cutting element and which lies in a plane parallel with the longitudinal axis of said stylet and which has at least one transverse dimension (measured from one side of the stylet head at the base of the cutting edge distally to the distal tip and proximally to a the base of the cutting edges at a diametrically opposite side of the stylet head) which is larger than at least one transverse dimension of the first tissue cutting element (see Figure 12).

Allowable Subject Matter

10. Claims 42-47 and 58-60 are allowable over the prior art of record.
11. Claims 49-54, 56 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
12. Claims 28-30, 32-38, 40, 41, 61 and 62 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st and 2nd paragraph, set forth in this Office action.

Response to Arguments

13. Applicant's arguments, see page 11 of the Remarks filed August 9, 2005, with respect to the rejections of claims 58 and 62 under 35 U.S.C. 112, first paragraph; the rejections of claims 28, 34-36 and 42 under 35 U.S.C. 102(e) as being anticipated by Bryan et al; the rejections of

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claims 58-60 under 35 U.S.C. 102(b) as being anticipated by Hofmann et al; and the rejections of claims 29-32, 38, 40, 41, 43-46, 49-52, 54, 56 and 57 under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Eggers et al. have been fully considered and are persuasive. Therefore, the aforementioned rejections have been withdrawn.

14. Applicant's arguments filed August 9, 2005 with respect to the rejection of claims 61 and 62 under 35 U.S.C. 112, first paragraph, and the rejection of claim 48 under 35 U.S.C. 102(e) as being anticipated by Bryan et al. have been fully considered but they are not persuasive.

Regarding the rejection of claims 61 and 62 under 35 U.S.C. 112, first paragraph, Applicant contends that support for the claimed features can be found in Figures 12-14 and on page 8, line 26 to page 9, line 8 of the present application. The Examiner respectfully disagrees. At no point in the disclosure of the instant application is the elongated cutter (142) disclosed as being slidably disposed within a shaft or slidable within an inner lumen of the shaft. The elongated cutter appears fixed to the interior lumen wall of the proximal portion of the shaft and is not disclosed as being capable of any movement independently thereof. The inner lumen of the shaft appears to be formed by the elongate cannula and the elongated cutter is mounted at the open distal end of the cannula. Therefore, the elongate cutter may be considered to be positioned in the inner lumen and longitudinally slidable with the proximal portion of the shaft, but the elongate cutter is always positioned distal to the inner lumen rather than slidable therein.

Regarding the rejection of claim 48 under 35 U.S.C. 102(e) as being anticipated by Bryan et al, Applicant contends that Bryant et al. do not teach or suggest a biopsy device having an electrosurgical cutting element on the distal end. While the Examiner concedes that Bryant et

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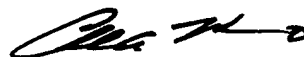
al. do not teach such a feature, claim 48 does not require that the claimed biopsy device have an electrosurgical cutting element on the distal end. Electrosurgical cutting elements are not required until claims 49 and 51. Therefore, the rejection of claim 48 under 35 U.S.C. 102(e) as being anticipated by Bryan et al. is maintained.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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September 28, 2005